

FORM PTO-1500
(REV. 11-2000)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

**TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371**

33809

U.S. APPLICATION NO. (if known, see 37 CFR 1.5

09/889752

INTERNATIONAL APPLICATION NO.
PCT/CH00/00027

INTERNATIONAL FILING DATE
January 19, 2000 (19.01.00)

PRIORITY DATE CLAIMED

January 20, 1999 (20.01.99)

**TITLE OF INVENTION PHARMACEUTICAL PREPARATION, CONTAINING SULFUR, MUSTARD SEEDS AND
A CUPRIC SALT, FOR TREATING RHEUMATIC SYNDROMES**

APPLICANT(S) FOR DO/EO/US

Norbert A. Geschwend and Norbert Geschwend

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: **certificate of mailing**

US PATENT AND TRADEOFFICE 09/889752	INTERNATIONAL APPLICATION NO PCT/CH00/00027	ATTORNEY'S DOCKET NUMBER 33809
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21. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO. \$1000.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$860.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$710.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$690.00 International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00 ENTER APPROPRIATE BASIC FEE AMOUNT =	CALCULATIONS PTO USE ONLY																									
Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492(e)). <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30	\$ 860.00 \$ 130.00																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">CLAIMS</th> <th style="width: 20%;">NUMBER FILED</th> <th style="width: 20%;">NUMBER EXTRA</th> <th style="width: 20%;">RATE</th> <th style="width: 20%;">\$</th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>16 - 20 =</td> <td>0</td> <td>x \$18.00</td> <td>\$ 0</td> </tr> <tr> <td>Independent claims</td> <td>1 - 3 =</td> <td>0</td> <td>x \$80.00</td> <td>\$ 0</td> </tr> <tr> <td colspan="4">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td>+ \$270.00</td> </tr> <tr> <td colspan="4">TOTAL OF ABOVE CALCULATIONS =</td> <td>\$ 270.00</td> </tr> </tbody> </table>	CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	Total claims	16 - 20 =	0	x \$18.00	\$ 0	Independent claims	1 - 3 =	0	x \$80.00	\$ 0	MULTIPLE DEPENDENT CLAIM(S) (if applicable)				+ \$270.00	TOTAL OF ABOVE CALCULATIONS =				\$ 270.00	\$ 270.00
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<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.	\$																									
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Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492(f)). <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30	\$																									
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Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +	\$																									
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	Amount to be refunded: \$																									
	charged: \$																									

a. ☒ A check in the amount of \$ 1260.00 to cover the above fees is enclosed.

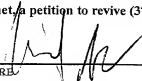
b. ☐ Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees.
 A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any
 overpayment to Deposit Account No. 160820. A duplicate copy of this sheet is enclosed.
 Order No. 33809

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card
 information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR
 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:
 Michael W. Garvey, Esq.
 Pearne & Gordon LLP
 526 Superior Avenue East, Suite 1200
 Cleveland, OH 44114-1484

SIGNATURE 
 Michael W. Garvey
 NAME
35878
 REGISTRATION NUMBER

WO 00/43021

PCT/CH00/00027

**PHARMACEUTICAL PREPARATION, , CONTAINING SULFUR, MUSTARD SEEDS
AND A CUPRIC SALT, FOR TREATING RHEUMATIC SYNDROMES**

This invention relates to a pharmaceutical preparation offering significantly improved properties in the treatment of rheumatic syndromes, especially rheumatism, arthritis, sciatica and/or gout, a cutaneous form of administration of a pharmaceutical preparation, a foot powder, as well as a method for producing a pharmaceutical preparation and, respectively, a foot powder.

Existing literature describes various active agents used in treating rheumatic and rheumatoid syndromes. For example, in a special supplement to "Zeitschrift für Ärztliche Fortbildung" (journal for advanced medical training), vol. XIII, 15 Nov 1959, No. 150, pages 798 to 802, titled "the practical physician", H. Seliger states that it is especially colloidal sulfur that has proved effective in treating rheumatism, arthritis and sciatica, among others. Beneficial additives mentioned by him include camphor and camomile flowers. H. Seliger makes special reference to a pharmaceutical preparation marketed by the N. Gschwend company of Herisau which contains the three active ingredients mentioned together with talcum as the carrier substance.

The monograph D. IT07.10.4 referred to in the bibliography of the IKS Monthly of 12/1994 describes mustard seed and camomile flowers as pharmaceutically effective substances in the cutaneous treatment of arthritis and rheumatic disorders.

Then there are a number of sulfur-containing preparations, indicated for "rheumatism", in the form of bath oils and additives with names such as "Soufrol", "Sulfur-Oil-Bath" and "Leukona Sulfomoor-Bath".

This invention is aimed at introducing another pharmaceutical preparation with good and/or improved properties for the treatment of rheumatic syndromes.

The active agents contained in the pharmaceutical preparation according to this invention for the treatment of rheumatic syndromes and especially rheumatism, arthritis, sciatica and/or gout include at least sulfur, mustard seed and a cupric salt.

The characterizing features of other preferred pharmaceutical compositions are specified in the subclaims.

The invention also covers a cutaneous form of administration, for the treatment of rheumatic syndromes, of a pharmaceutical preparation per this invention. The cutaneous form of administration preferably employs a fine-particle foot powder specially prepared for application on the sole of the foot.

The preferred fine foot powder is sprinkled into shoes, socks, stockings or liners whereupon the active ingredients are absorbed into the blood stream through the sole of the foot. This is a unique form of applying a rheumatism antidote and constitutes a particular aspect directly associated with the special combination of the individual active ingredients as proposed by this invention. The functional mechanism is based on the fact that, as the substance makes contact with live and keratinous tissue (that being the sole of the foot), a number of chemical transformations take place, aided by the effect of natural aspiration, even natural perspiration, leading to corresponding reactions in two

ways, i.e. by way of both the blood stream and the nerve tissue. As an obvious prerequisite, the active agents must be adequately resorbed by the skin, which is assured by the particular combination of active ingredients per this invention. By virtue of the above-mentioned transdermal absorption the organism will only take up exactly the amount of active substances that it needs.

Key components of the compounds introduced by this invention are such active ingredients, present in trace amounts only, as cupric salt which preferably consists of copper sulfate, and potassium iodate, to both of which a certain catalytic effect is attributed. Correspondingly, these two substances, in conjunction with talc as the carrier substance, form a so-called "catalytic powder" which is added in minuscule amounts to the other active agents including in particular sulfur and mustard seed.

The process of producing the pharmaceutical preparation begins with a first step in which talc is mixed with sulfur as the active agent plus, as an option, camphor and camomile flowers. For the blending operation the active ingredients are prepowderized and, of course, the talc, or talcum, constituting the carrier substance, is pulverulent on its part.

As the second step of the process, a minuscule amount of the above-mentioned so-called "catalytic powder" is added to the mixture. The catalytic powder again consists of talc as well as mustard seed, the cupric salt preferably in the form of copper sulfate, and, as an option, potassium iodate.

The advantage of adding potassium iodate derives in particular from the fact that it stabilizes the pharmaceutical preparation for use in hot or tropical regions. The talcum carrier substance is known to be less than absolutely stable or suitable for use in tropical or hot zones, which makes the addition of potassium iodate necessary or advisable.

The following explains this invention in more detail with the aid of the production-process examples given below and with reference to a sample composition.

As mentioned above, the production follows a bipartite process, i.e. the pharmaceutical preparation according to this invention is produced in two steps, dividing the composition into two parts.

Part 1:

Sulfur:	Approx. 30 – 50 % by weight, preferably 30 – 40 % by weight;
Camomile:	0 – 10 %, preferably 5 – 10 %;
Camphor:	0 – 25 %, preferably 15 – 25 %;
Talcum (balance):	20 – 65 %.

Total, Part 1: 85 – 95 %

Part 2:

Mustard seed:	0.5 – 2.5 %, preferably 1 – 1.5 %;
Copper sulfate:	0.05 – 0.3 %, preferably 0.1 – 0.15 %;
Potassium iodate:	0 – 0.15 %, preferably 0.05 – 0.1 %
Talcum:	3 – 13 %

Total, Part 2: 5 – 15 %

The quantities expressed in percent by weight relate to the total weight of the preparation composed of Part 1 and Part 2.

For producing the preparation, the first step is to mix Part 1 for which purpose the individual components are ground into ultrafine powder and screened, then blended with talc in a mixer, for instance a so-called 4-way mixer, for about 15 minutes.

Part 2 is produced by first grinding copper sulfate and, if applicable, potassium iodate in a mortar using a pestle until a homogeneous powder is obtained. These components are then sifted, together with talc and mustard seed, for instance through a 0.5mm-mesh screen and are then added to and blended with the mixture of Part 1. This can again be performed in a 4-way mixer, in this case for about 20 minutes.

Of course, the above quantities are indicated as examples only, subject to variation and modification depending on the application i.e. form of administration and on the ailment to be treated. Likewise, the mixtures can naturally be produced by methods deviating from that described above. It is important, however, that especially when a foot powder is produced, the different components making up the foot powder be thoroughly mixed

It is also possible to administer the preparation in the form of a cream, paste or the like, containing the pharmaceutical preparation for instance as an ultrafine powder together with carrier substances and other additives.

Sciatica, muscular rheumatism, arthritis, phlebitis (inflammation of a vein), excessively high or low blood pressure, paralysis deformans, paralysis post myelitis, poliomyelitis, paralysis cerebrales, paralysis post nephritis vel uraemia, paralysis postlaesion cause alicuius mechanica, eczema, and x-ray burns.

Patent Claims:

1. Pharmaceutical preparation for treating rheumatic syndromes, especially rheumatism, arthritis, sciatica and/or gout, characterized in that it contains at least the following active agents:
Sulfur, mustard seed as well as a cupric salt.
2. Pharmaceutical preparation especially as per claim 1, characterized in that the cupric salt employed is copper sulfate.
3. Pharmaceutical preparation especially as per claim 1 or 2, additionally containing camomile and preferably camomile flowers.
4. Pharmaceutical preparation especially as per one of the claims 1 to 3, containing talc as its carrier substance.
5. Pharmaceutical preparation especially as per one of the claims 1 to 4, additionally containing camphor.
6. Pharmaceutical preparation especially as per one of the claims 1 to 5, additionally containing potassium iodate.
7. Pharmaceutical preparation especially as per one of the claims 1 to 5, characterized in that the preparation is produced in powder form.
8. Pharmaceutical preparation especially as per one of the claims 1 to 7, characterized by the following volume concentrations of the various components:

Sulfur: 30 – 50 % by weight, preferably 30 – 40 % by weight;
Camomile: 0 – 10 % by weight, preferably 5 – 10 % by weight;
Camphor: 0 – 25 % by weight, preferably 15 – 25 % by weight;
Mustard seed: 0.5 – 2.5 % by weight, preferably 1 – 1.5 % by weight
Copper sulfate: 0.05 – 0.3 % by weight, preferably 0.1 – 0.15 % by weight;
Potassium iodate: 0 – 0.15 % by weight, preferably 0.05 – 0.1 % by weight;
Talc making up the remainder up to 100 % by weight.

9. Cutaneous form of administration employing a pharmaceutical preparation per one of the claims 1 to 8.
10. Cutaneous administration especially as per claim 9, characterized in that it is in the form of a foot powder suitable for application on the sole of the foot.
11. Process for producing a pharmaceutical preparation as in one of the claims 1 to 9, characterized in that, in a first step, talc and sulfur are mixed in powder form, followed by a second step in which a small amount of a so-called "catalytic powder" is added, said catalytic powder being a pulverulent mixture composed of talc, mustard seed and a cupric salt, especially copper sulfate.
12. Process especially as in claim 11, characterized in that in the first phase, camphor and/or camomile in the form of camomile flowers are optionally added and that in the second phase potassium iodate is further added to the "catalytic powder".

13. Process especially as per claim 11 or 12, characterized in that in the first phase the components are first mixed in powder form in a mixer such as a 4-way mixer, following which the components to be added in the second step are screened and added in powder form to, and thoroughly blended with, the mixture of the first phase.
14. Application of the process per one of the claims 11 to 13 for producing a foot powder serving to treat rheumatic syndromes especially such as rheumatism, arthritis, sciatica and/or gout.
15. Use of the pharmaceutical preparation per one of the claims 1 to 8 for treating especially one of the following disorders or ailments:

Sciatica, muscular rheumatism, arthritis, phlebitis (inflammation of a vein), excessively high or low blood pressure, paralysis deformans (a degenerative, chronic, not acutely inflammatory disease of a joint), paralysis post myelitis (inflammation of the spinal cord), poliomyelitis (polio), paralysis cerebri (brain-related paralysis), paralysis post nephritis vel uraemia (paralysis following a kidney infection or poisoning of the urinary tract), paralysis post laesion cause alicuius mechanica (paralysis following injuries/lesions after surgical procedures, a fall, impact etc.), eczema, and/or x-ray-induced burns.

P 200 948



DECLARATION AND POWER OF ATTORNEY OR UTILITY OR DESIGN PATENT APPLICATION

☐ Submitted with Initial Filing

☒ Submitted after Initial Filing
(Surcharge (37 CFR 1.16(e)) required)

Attorney Docket No.: 33809

Application Number: 09/889,752

First Named Inventor: Norbert A. Gschwend

Filing Date: July 20, 2001

Group Art Unit: _____

Examiner Name: _____

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

"PHARMACEUTICAL PREPARATION, CONTAINING SULFUR, MUSTARD SEEDS
AND A CUPRIC SALT, FOR TREATING RHEUMATIC SYNDROMES"

the specification of which (check only one item below)

☐ is attached hereto,

OR

☒ was filed on (MM/DD/YYYY) January 19, 2000, as United States Application Number or PCT International Application Number PCT/CH00/00027 and was amended on (MM/DD/YYYY) ____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d), or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

<u>Country</u>	<u>Prior Foreign Application Number(s)</u>	<u>Foreign Filing Date (MM/DD/YYYY)</u>	<u>Priority Claimed?</u>
EU	99 100 923 4	January 20, 1999	Yes

As a named inventor, I hereby appoint practitioners at Customer No. 000116 as my attorneys to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

Address all correspondence to Customer Number 000116.

Please direct all correspondence and inquiries to Michael W. Garvey at (216) 579-1700.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

(1) Inventor Name (sole or joint): Norbert A. Gschwend

Signature: Norbert A. Gschwend

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Signature: N. Geschwend

Date: 24/10/2001

Citizenship: Switzerland

Residence (City, State, Country): Herisau, Switzerland C1+k

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